UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CSPC PHARMACEUTICAL GROUP LIMITED,
CSPC OUYI PHARMACEUTICAL CO., LTD., AND
CONJUPRO BIOTHERAPEUTICS, INC.,
Petitioners,

v.

IPSEN BIOPHARM LTD.,
Patent Owner.

Case No. IPR2025-00505
Patent No. 11,344,552

PETITIONERS' MOTION TO EXCLUDE PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)

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Pursuant to 37 C.F.R. § 42.64(c), and the Scheduling Order (Paper 14), Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjurpro Biotherapeutics, Inc. (collectively, "Petitioners") move to exclude Patent Owner Ipsen Biopharm Ltd.'s ("Patent Owner") Exhibits 2002-2003, 2005-2011, 2013-2015, 2020-2035, 2037, 2039-2042, 2047-2072, 2074-2075 ("the Exhibits"), which are inadmissible under the Federal Rules of Evidence ("FRE"). Therefore, Petitioners respectfully request the Board exclude the Exhibits.

ARGUMENT

A motion to exclude must explain why evidence is admissible under the FRE (*e.g.*, relevance or hearsay). *Legend3D, Inc. v. Prime Focus Creative Servs. Can. Inc.*, IPR2016-00806, Paper 73 at 8-9 (PTAB Sept. 18, 2017); *see* 37 C.F.R. §§ 42.62, 42.64; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,758, 48,767 (Aug. 14, 2012) (noting parties may submit motions to exclude regarding evidence "believed to be inadmissible"). Evidence that is not relevant is not admissible. Fed. R. Evid. 402. Evidence is relevant if it has any tendency to make a fact of consequence more or less probable than it would be without the evidence. Fed. R. Evid. 401. Furthermore, evidence may be excluded if its probative value is substantially outweighed by a danger of unfair prejudice, confusion of the issues, or misleading the Board. Fed. R. Evid. 403.

I. Exhibit 2004

Petitioner moves to exclude Exhibit 2004 as not being relevant to any issue on which trial has been instituted, for causing confusion and undue prejudice, and for containing hearsay. Exhibit 2004 is an article entitled "Pancreatic cancer and FOLFIRINOX: a new era and new questions." Patent Owner relies on Exhibit 2004 to claim that only 85 mg/m^2 of oxaliplatin could be used when treating patients with FOLFIRINOX. (Paper 21 at 27-28.) Because Patent Owner is relying on statements for the truth of the matter asserted, these statements are hearsay not subject to any exception.

In addition, any statements from Exhibit 2004 relied upon by Patent Owner related to FOLFIRINOX dosing are irrelevant, confusing, and unduly prejudicial. In fact, Exhibit 2004 does not, contrary to Patent Owner's suggestion, indicate that any individual understood FOLFIRINOX regimens to be limited to any particular dosing and/or limited to 85 mg/m^2 of oxaliplatin. Rather, Exhibit 2004 states that to manage FOLFIRINOX toxicity concerns, "[a]s with usual practice, reduction in individual drug dosage is a standard approach for many of the common complications." (Ex. 2004 at 2.) Exhibit 2004 also states that physicians at Yale reported "dose reductions were common" for oxaliplatin, irinotecan, and 5FU. (*Id*. at 3 (further including Table 2, which shows multiple reference modifying FOLFIRINOX regiments by dropping

oxaliplatin and other drugs).) Exhibit 2004 also states that one study found that 81% of patients required a dose reduction, but "that this did not affect results) and that "the majority of regimens presently under investigation incorporate some modification of [FOLFIRINOX]." (*Id*. at 4.)

Because Patent Owner timely objected (Paper 16) and Exhibit 2004 is irrelevant, confusing, prejudicial, and contains hearsay, (FRE 401-403, 801-802), it should be excluded.

II. Exhibits 2008 and 2009

Petitioner moves to exclude Exhibits 2008 and 2009 as not being relevant to any issue on which trial has been instituted, for causing confusion and undue prejudice, for containing hearsay, and for lack of authentication. As described herein, Patent Owner does not cite either Exhibit 2008 or 2009 in its briefing but only to several paragraphs in Dr. Oberstein's declaration, (Paper 21 at 48-49), and a single paragraph within Oberstein's declaration, paragraph 297, includes a citation to both exhibits. (*See* Exhibit 2076, ¶ 297.)

Exhibit 2008 is entitled "Clinical Development Success Rates 2006-2015" and appears to be literature from the Biotechnology Innovation Organization ("Bio"). (*See* Ex. 2008.) Exhibit 2009 is an article entitled "Preclinical Rational for the Phase III Trials in Metastatic Pancreatic Cancer." (*See* Ex. 2009.) Patent Owner

and its expert rely on both exhibits to claim that new clinical trials of oncology drugs face low likelihoods of approval and high fail rates. (*See* Ex. 2076, ¶297.) First, the statements from these exhibits are used for the truth of the matter asserted and thus constitute hearsay not subject to any hearsay exception. FRE 801-802. Second, these exhibits both relate to the success of clinical trials, not the obviousness of a drug combination, which are two very different standards. Therefore, use of such evidence is likely to cause confusion and create undue prejudice. Third, both exhibits note that pockets of data was not considered when evaluating success rates. (*See* Ex. 2008 at 6 (noting only certain studies were included in analysis); Ex. 2009 at 4 (noting some data may be unpublished or only in abstract form and thus not used).) Exhibit 2008 also notes that success rates may be increased through various means, including new delivery technologies. (Ex. 2008 at 23.) That is, use of liposomal derivatives of known compounds, like those used here, could affect success rates.

Finally, Patent Owner has not provided any evidence that either exhibit is an authentic document published and available prior to the priority date.

Because Patent Owner timely objected (Paper 16) and Exhibits 2008-2009 are irrelevant, confusing, prejudicial, contain hearsay, and are not authenticated (FRE 401-403, 801-802, 901-902), they should be excluded.

III. Exhibit 2010

Petitioner moves to exclude Exhibit 2010 as being irrelevant to any issue on which trial has been instituted, for causing confusion and undue prejudice, and for containing hearsay. As described herein, Patent Owner does not cite to Exhibit 2010 in its briefing but only to several paragraphs in Dr. Oberstein's declaration, (Paper 21 at 48-49), and a single paragraph within Oberstein's declaration, paragraph 299, includes a citation to both exhibits. (*See* Exhibit 2076, ¶ 299.)

Exhibit 2010 is entitled "Phase II Oncology Trials: Let's Be Positive." (*See* Ex. 2010.) Patent Owner and its expert rely on Exhibit 2010 to claim that phase II clinical trials of oncology drugs have a low predictive value of FDA approval. (*See* Ex. 2076, ¶299.) First, the statements relied upon are used for the truth of the matter asserted and thus constitute hearsay not subject to any hearsay exception. FRE 801-802. Second, this exhibit compares clinical trial success and FDA approval, neither of which relate to whether a proposed drug combination is obvious. Therefore, use of such evidence is likely to cause confusion and create undue prejudice.

Because Patent Owner timely objected (Paper 16) and Exhibit 2010 is irrelevant, confusing, prejudicial, and contains hearsay, (FRE 401-403, 801-802), it should be excluded.

IV. Exhibits Never Relied Upon Should Be Excluded.

Petitioner moves to exclude exhibits not cited in substantive briefing by Patent Owner. Specifically, Exhibits 2002–2003, 2005–2011, 2013–2015, 2020–2028, 2030, 2033-2035, 2037, 2039–2042, 2047–2072, and 2074–2075 are not discussed or cited anywhere in Patent Owner's Response (Paper 21) or Patent Owner's Sur-Reply (Paper 38). If Patent Owner could not identify a use for these exhibits in their own papers, the exhibits have no tendency to make any fact of consequence more or less probable, and they are therefore irrelevant. Therefore, they are irrelevant to any issues in this proceeding, would cause confusion, and create undue prejudice and should be excluded.

Reliance on Patent Owner's declaration from Dr. Paul Oberstein in this proceeding does not remedy this issue. First, Dr. Oberstein's declaration fails to cite to numerous exhibits in this proceeding, that include most of those not cited in the Patent Owner's briefing, including Exhibits 2001–2003, 2005, 2011–2013, 2016, 2020–2022, 2024–2025, 2027–2028, 2035, 2037, 2047–2049, 2053, 2055–2061, 2063, 2065–2070. Therefore, several of these exhibits are not cited in any discussion. Those that are cited solely by Oberstein are not substantively discussed and Patent Owner does not sufficiently develop the contentions or arguments related to these exhibits.

Permitting Patent Owner to introduce dozens of uncited exhibits into the record creates the risk that the Board may inadvertently consider evidence that Petitioner has had no meaningful opportunity to address. Because Patent Owner never explained the significance of these exhibits, Petitioner was unable to respond to whatever arguments Patent Owner may have intended to advance. Allowing such evidence to remain in the record would be fundamentally unfair and would undermine the integrity of the adversarial process.

Patent Owner timely objected to the non-use of exhibits in pleadings (Paper 16) and any non-use of exhibits should be cause for exclusion. Therefore, as explained herein, these exhibits are irrelevant, confusing, prejudicial, and contain hearsay, (FRE 401-403, 801-802), and should therefore be excluded.

V. CONCLUSION

For the reasons set forth above, Petitioners respectfully request that the Board exclude Exhibits 2001–2003, 2005–2011, 2013–2016, 2020–2035, 2037, 2039–2042, 2047–2075.

Respectfully submitted,

Dated: April 27, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned hereby certifies that on April 27, 2026, the foregoing Petitioners' Motion to Exclude Patent Owner's Evidence Pursuant to 37 C.F.R. § 42.64(c) and supporting exhibits were served via email, as authorized by the Patent Owner, at the following email addresses:

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